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Financing the US Biopharmaceutical Industry
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From the late 1990s through 2007, the US biotechnology industry was booming. According to Ernst & Young's annual global biotechnology reports (www.ey.com/beyondborders), measured in 2007 dollars, US biotechnology revenues increased steadily from $19.3 billion in 1996 to $68.4 billion in 2007, while R&D spending in the industry increased from $10.4 billion in 1996 to $30.0 billion in 2007. In 1996 the industry had 1,287 biotech firms, of which 294 were publicly listed; and in 2007 1,502 companies, of which 386 were publicly listed. In the interim, at least 128 US venture-backed biotech companies were acquired by established companies. Year-end employment in the US biotechnology industry was, not counting biotech employees in traditional "Big Pharma" companies, 118,000 in 1996 and 192,700 in 2007.

Yet, as Gary Pisano has shown in his 2006 book, *Science Business: The Promise, the Reality, and the Future of Biotech*, over its 30-year history the profitability of the biopharmaceutical (BP) industry as a whole has been low. Product development in the BP industry can cost up to $2 billion over a time-frame of 10-20 years, with highly uncertain prospects for a commercial product. Nevertheless, at least until the financial crisis of 2008, the BP industry has received large amounts of business funding from private equity, R&D contracts, M&A deals, and initial public offerings. Why have venture capitalists, big pharma, and public investors been investing so heavily in an industry in which profits are so difficult to generate? The research project on which the proposed paper will be based seeks to answer this question, and in the process provide a basis for understanding the sustainability of innovation in the US BP industry, including how the industry will adapt to the current financial crisis.

This project focuses on the modes of financing the US biotechnology industry that have supported the formation and growth of innovative biopharmaceutical (BP) enterprises. The research for this project constitutes a financial history, brought up to the present, of a leading US high-technology industry. It integrates the role of finance with our knowledge of BP innovation.

The project provides new insights into the ways in which public policy – for example, drug-rpice regulation, or sharing of the costs of and gains from innovation between business and government – can support or undermine high-tech innovation in the United States. In a period of financial instability in which the BP industry remains a strength of the US economy, it is important to ensure that US financial regulations and institutions promote innovative investments that result in drugs that people need at prices that the healthcare system can afford.

Finance is a vital but often neglected topic in research on the innovation process. Committed finance is needed to sustain a cumulative and collective process of transforming technology and

accessing markets from the time investments in productive resources are made until the time that financial returns are generated. Research on the finance of innovation seeks to identify the sources of committed finance and the conditions under which it remains committed to the innovation process until new commercial products become available at affordable prices. Financial commitment cannot be taken for granted. Under certain economic conditions and in the presence of certain types of financial institutions, those with financial claims on the innovative enterprise may be able to extract value in ways that undermine the innovation process.

In this project, the "finance of industry" is broadly construed to include not only equity investments and securities issues, but also retentions out of profits, government investments in physical infrastructure and the knowledge base, and government subsidies. Our proposed paper will examine the roles of investments in the knowledge base by the National Institutes of Health and government subsidies under the Orphan Drug Act of 1983 in providing a foundation for business-sector investment. In particular we will analyze the determinants of commercial success of the 31 "blockbuster" BP drugs to date.

The proposed paper will summarize our results in three research areas: 1) cost of drug development, 2) financing of entrepreneurial startups, and 3) financial behavior of established BP companies. In each case, we seek to identify the institutional and organizational arrangements that support or undermine investments in the drug development process by observing BP business strategies and decisions. By constructing a series of historical case studies of the finance of BP drug development, our research identifies the different parties in government and business who have borne the burden of these costs. We are building a database of the 336 private equity-backed biotech IPOs that, according to Venture Xperts, have taken place in the United States from 1979 through 2007. For the first time in any calendar year, given a dampening of stock market speculation, there were no BP IPOs in 2008). This database will enable us to determine, among other things, whether and to what extent the biotech IPOs that have been more lucrative for pre-IPO investors have ultimately been the most successful in the development of commercial products. We are also building a similar database on M&A deals in biotech, going back to 1986.

Our research on the financial behavior of established corporations analyzes the impact of an orientation toward maintaining the value of a company's stock price, particularly through stock buybacks, on that firm's innovative capability and product development. Among big pharma, in the period 2000-2007, Merck did buybacks equal to 57 percent of R&D expenditures, Pfizer 82 percent, and Johnson & Johnson 60 percent. When the substantial dividends issued by big pharma companies are added to their repurchases, the ratio of distributions to shareholders to R&D expenditures for 2000-2007 shoots up to 148 percent at Merck, 148 percent at Pfizer, and 116 percent at Johnson & Johnson. Meanwhile, Amgen, the largest dedicated BP firm, did $20.3 billion in repurchases over this period, an amount that was $98 million more than it spent on R&D. Genentech, the second largest DBF, did $6.6 billion in repurchases in 2000-2007, equivalent to 83 percent of the funds that it spent on R&D. We compare R&D efforts and innovative outcomes of BP companies that are large stock repurchasers with those that are not. Through this research, we address the central policy issue of whether higher drug prices in the United States than abroad are warranted by the need for BP companies to spend on R&D.